



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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re Application of: Ke et al.)

Serial No.: 09/736,051)

Filed: December 13, 2000)

For: COMBINATION THERAPY FOR)
OSTEOPOROSIS)

Group Art Unit: 1654

Conf. No. 6748

Examiner: Leary, L.

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Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' BRIEF

Applicants appeal from the final rejection mailed February 4, 2003.

I. REAL PARTY IN INTEREST

The real party in interest is the assignee of the application, Pfizer Inc., New York, New York.

II. RELATED APPEALS AND INTERFERENCES

Insofar as counsel is aware, there are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-4, 6-14, 16-30, 33-42, 45-50, 52-55, 57-62, 65-69, 72-75, 79-80, 84-89 and 92-108 are pending. Claims 5, 15, 31-32, 43-44, 51, 56, 63-64, 70-71, 76-78, 81-83, and 90-91 are canceled. Claims 93-108 are appealed, a copy of which appears in the attached Appendix A.

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IV. STATUS OF AMENDMENTS

There were no amendments filed subsequent to final rejection.

V. SUMMARY OF INVENTION

The invention of the appealed claims concerns a combination of an estrogen agonist/antagonist and a growth hormone secretagogue (page 1, lines 1-3; page 16, lines 10-11; page 32, lines 26-30). This combination of drugs is useful for the treatment of conditions resulting in low bone mass, such as osteoporosis (page 4, lines 17-20).

The invention is further directed to a process for making a pharmaceutical composition by combining an estrogen agonist/antagonist, a growth hormone secretagogue, and a pharmaceutically acceptable carrier (page 48, lines 1-3; page 50, lines 21-25; page 51, lines 3-7 and 19-22).

VI. ISSUES

Whether Claims 93-108 were timely filed under 35 U.S.C §135(b).

VII. GROUPING OF CLAIMS

For purposes of this appeal, rejected claims 93-108 may be treated as a single group.

VIII. ARGUMENTS

The sole remaining issue in this application is whether Applicants' claims 93-108 were timely filed under 35 USC § 135 (b). The Examiner found that these claims were copied from US Patent 6,043,026, which issued March 28, 2000. The Examiner then

found that the claims were not timely presented because the date of receipt of the claims in the PTO was one year and one day after the issuance of the '026 patent.

Yet proper application of 37 CFR § 1.8 shows that the claims were timely filed. Applicants added claims 93-108 in the Amendment Under 37 C.F.R. § 1.607 mailed on March 27, 2001 (copy attached as Appendix B). The Examiner accords the receipt date of March 29, 2001 as the date on which the claims were filed with the Office. Yet, Applicants are entitled to the mailing date of March 27, 2001 because it is on this date that the claims were mailed to the Office in compliance with the Certificate of Mailing provisions of 37 C.F.R. § 1.8. Because March 27, 2001 is less than one year from the date of issuance of the '026 patent, the claims were timely filed and the rejection under section 135(b) should be reversed.

Under 37 C.F.R. § 1.8, an Applicant is entitled to the date of mailing if the document includes a Certificate of Mailing:

37 CFR § 1.8 Certificate of mailing or transmission.

(a) Except in the cases enumerated in paragraph (a)(2) of this section, correspondence required to be filed in the Patent and Trademark Office within a set period of time will be considered as being timely filed if the procedure described in this section is followed. The actual date of receipt will be used for all other purposes.

(1) Correspondence will be considered as being timely filed if:

(i) The correspondence is mailed or transmitted prior to expiration of the set period of time by being:

(A) Addressed as set out in § 1.1(a) and deposited with the U.S. Postal Service with sufficient postage as first class mail; or

(B) Transmitted by facsimile to the Patent and Trademark Office in accordance with § 1.6(d); and

(ii) The correspondence includes a certificate for each piece of correspondence stating the date of deposit or transmission. The person signing the certificate should have reasonable basis to expect that the correspondence would be mailed or transmitted on or before the date indicated. ...

Applicants complied with Rule 1.8 when submitting claims 93-108. The claims were submitted in an amendment mailed on March 27, 2001, which is less than one year from the issuance of U.S. Patent No. 6,043,026. That amendment included a certificate of mailing addressed as in 37 C.F.R. § 1.1(a) and was deposited with sufficient postage as first class mail. Clearly, the document had sufficient postage because the Examiner admits that it was received on March 29, 2001, which is only two days after its mailing. Pursuant to 37 C.F.R. § 1.8 (a)(1)(ii), the amendment included a certificate stating that it was deposited on March 27, 2001 and was signed by a person having reasonable expectation that the amendment would be mailed on that date. Jean M. Marshall, an administrative assistant at Connolly, Bove, Lodge and Hutz LLP, signed the certificate. Ms. Marshall then sealed the amendment in an envelope addressed to the Commissioner for Patents and deposited the envelope with mailroom personnel at Connolly Bove Lodge and Hutz LLP with the reasonable expectation that they would follow their standard, daily procedure to deposit the envelope along with other outgoing mail with the U.S.

Postal Service before the end of the day. Thus, because the procedures of 37 C.F.R. § 1.8 were followed, Applicants respectfully submit that the claims mailed on March 27, 2001 were timely filed before March 28, 2001.

The Examiner argues that the certificate of mailing procedures of Rule 1.8 cannot be complied with absent "a certified copy of the certificate of mailing issued by the US Postal Office" (Final Office Action mailed February 4, 2003, page 2). Furthermore, the Examiner faults Applicants for failing to provide "official evidence" that the amendment was filed with the U.S. Postal Service prior to expiration of the one year time period (*id.*). The Examiner requests "an official copy of the certificate of mailing issued by the US Postal Office on March 27, 2001 or March 28, 2001" (Advisory Action mailed May 22, 2003, page 2). Yet no statutory or regulatory support for these requirements is cited in the Office Action, and Applicants know of no such support. The Examiner seems to be requiring a certification issued by the US Postal Service. However, Rule 1.8 does not require any document signed or certified by the US Postal Service.

Section 512 of the MPEP provides that when a paper is received in the U.S. Patent and Trademark Office after the end of the period for reply, the paper should be inspected to determine if a certificate of mailing or of transmission has been included. In those instances where a certificate of mailing or of transmission does appear in the paper, a check should be made to determine whether the indicated date of deposit or transmission is within the period for reply. If the date indicated in the certificate is after the end of the period for reply, the paper is untimely and no notation of the date need be made. Where the date indicated on the certificate is within the period for reply, the paper should be considered to be timely filed.

The amendment, including the claims that were rejected as not timely filed, was accompanied by a certificate of mailing dated March 27, 2001. Accordingly, under MPEP 512, the Examiner should have done nothing more to accept the document as timely filed than to check that the indicated date appearing on the certificate of mailing was within the reply period.

IX. CONCLUSION

For the above reasons, Applicants respectfully request that the rejections be withdrawn and that an interference be declared between the present application and the '026 patent and any continuing or divisional applications thereof.

The Notice of Appeal was filed on June 2, 2003. Accordingly, Applicants request a two-month extension of time under 37 C.F.R. § 1.136(a) to file the Appeal Brief. A fee authorization to charge Deposit Account No. 03-2775 is enclosed for \$750.00 to cover the fee set forth in 37 C.F.R. § 1.17(c) plus the fee for a two-month extension of time. Should there be additional fees associated with this filing, the Commissioner is hereby authorized to charge Deposit Account No. 03-2775. This brief is being submitted in triplicate.

Respectfully submitted,

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